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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/075,597	02/15/2002	Roy Sanders	2880/360	9386
23838	7590	04/05/2005	EXAMINER	
KENYON & KENYON 1500 K STREET, N.W., SUITE 700 WASHINGTON, DC 20005			ROBERT, EDUARDO C	
			ART UNIT	PAPER NUMBER
			3732	

DATE MAILED: 04/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	Application No. 10/075,597	Applicant(s) SANDERS ET AL.	
	Examiner Eduardo C. Robert	Art Unit 3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 March 2005.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 3-16 is/are pending in the application.
- 4a) Of the above claim(s) 6-8, 10-13 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-5, 9, 14 and 15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

The finality of the last office action has been withdrawn and the amendment filed on March 17, 2005 has been entered. A new Office action follows:

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tormala et al. (U.S. Patent No. 6,015,410) in view of Yamamoto (EPO Patent No. 0430563 cited by applicant).

Tormala et al. disclose a surgical screw which is bioabsorbable in vivo and comprises an elongated shank with threads, a head perpendicular to a longitudinal axis of the shank, and the shank protruding from the head (see Figure 3 below). The head comprises a recess which can be any shape as shown in Figures 4A-4C, e.g. 51, 54, 52, 55, 53, in the proximal surface and the recess has a cross-section with a rotational symmetry around the longitudinal axis of the shank and wherein the recess has an odd number of rounded lobes, i.e. 3, extending away from the center of the head. The screw comprises self-reinforced material (see col. 7, lines 20-23). The head has a distal surface that tapers toward the shank (see Figure 3 above). With regard to claim 3, it is noted that the screw of Tormala et al. is made by machining (see col. 7, lines 34-35) and

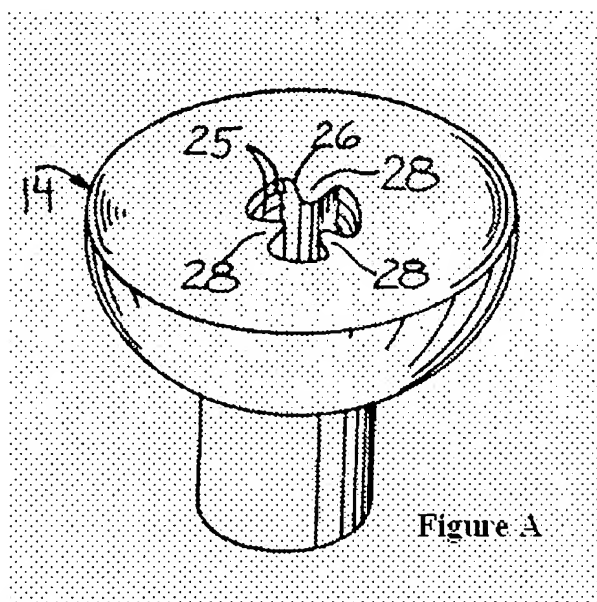
this includes clearly the formation of the recess. Tormala et al. disclose the claimed invention except for the recess having a shape that includes lobes that are ovals, circular or rectangular with rounded edges. Yamamoto discloses a surgical screw with a recess having a shape that includes lobes that substantially resemble an oval (see Figure 7). One of the purposes of having a recess, as shown by Yamamoto, is to provide the screw with a high and stable conversion efficiency of torque. It would have been obvious to one skill in the art at the time the invention was made to construct the screw of Tormala et al. with a recess in view of Yamamoto, in order to provide the screw with a high and stable conversion efficiency of torque.

Claims 1, 3-5, 9 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tormala et al. (U.S. Patent No. 6,015,410) in view of Hodorek (U.S. Patent 5,167,664).

Tormala et al. disclose a surgical screw which is bioabsorbable in vivo and comprises an elongated shank with threads, a head perpendicular to a longitudinal axis of the shank, and the shank protruding from the head (see Figure 3 below). The head comprises a recess which can be any shape as shown in Figures 4A-4C, e.g. 51, 54, 52, 55, 53, in the proximal surface and the recess has a cross-section with a rotational symmetry around the longitudinal axis of the shank and wherein the recess has an odd number of rounded lobes, i.e. 3, extending away from the center of the head. The recess will accept a insertion tool which match the recess shape. The screw comprises self-reinforced material (see col. 7, lines 20-23). The head has a distal surface that tapers toward the shank (see Figure 3 above). It is noted that the screw of Tormala et al. is made by machining (see col. 7, lines 34-35) and this includes clearly the formation of the recess. Tormala et al. disclose the claimed invention except for the recess having a cloverleaf shape and insertion device matching the cloverleaf recess. Hodorek discloses a bone screw comprising an

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elongated shank 12 with threads, a head 14 having a proximal surface perpendicular to a longitudinal axis of the shank, and the shank protrudes from the head (see Figure 2). The head comprises a recess, e.g. 26, having a cross-section with a rotational symmetry around the longitudinal axis and wherein the recess includes an odd number of rounded lobes extending away from the center of the head (see Figure A below). It is noted that the lobes are formed from ovals located on the recess, thus forming a cloverleaf shape (see Figure A below). Hodorek further discloses an inserter which is used with the recess of the head 14 (see col. 2, lines 34-37).



It would have been obvious to one skill in the art at the time the invention was made to construct the screw of Tormala et al. having a cloverleaf shape and use of a matching insertion tool in view of Hodorek instead of the recess having any other shape such as triangular, or circular or square, etc., as such would merely constitute substitution of functionally equivalent recess and insertion tools. Moreover, merely changing the shape of the recess is anything more than one of numerous

shapes or configurations a person ordinary skill in the art would find obvious. In re Dailey and Eilers, 149 USPQ 47 (1966).

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tormala et al. (U.S. Patent No. 6,015,410) in view of Hodorek (U.S. Patent 5,167,664) as applied to claim 14 above, and further in view of Hemer (U.S. Patent 5,019,080).

The combination of Tormala et al. and Hodorek discloses the claimed invention except for a distal end of the inserter being progressively smaller towards the distal tip of the distal end. Hemer teaches to construct a distal end of an inserter 20 being progressively smaller toward a distal tip of the distal end in order to prevent possible wobbling of the screw when driven by the inserter (see Figure 1 and col. 4, lines 25-33, col. 5, lines 1-6, col. 3, lines 1-3, and 31-35). It would have been obvious to one skill in the art at the time the invention was made to construct the screw of the combination of Tormala et al. as modified by Hodorek with the inserted distal end being progressively smaller towards the distal tip of the distal end in view of Hemer, in order to prevent wobbling of the screw when it is driven by the inserter.

### ***Response to Arguments***

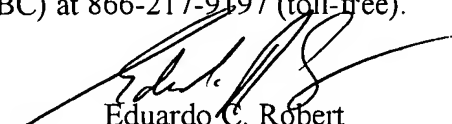
Applicant's arguments, see amendment, filed on 3/17/05, with respect to the rejection(s) of claim(s) 1, 3-5, 9, 14, and 15 under 102 and 103 rejections have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made (see rejections above).

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eduardo C. Robert whose telephone number is 571-272-4719. The examiner can normally be reached on Monday-Friday, 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin P. Shaver can be reached on 571-273-4720. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Eduardo C. Robert  
Primary Examiner  
Art Unit 3732

E.C.R.